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EXAMINER	
UNGAR, SUSAN NMN	

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12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/834,794	Applicant(s) Papsidero et al
	Examiner Ungar	Art Unit 1642

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *three* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on *Aug 11, 2003*.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) *1-4, 9, 22, and 26-28* is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) *1-4, 9, 22, and 26-28* is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

1. The Amendment filed August 11, 2003 (Paper No. 11) in response to the Office Action of February 11, 2003 (Paper No. 9) are acknowledged and have been entered. Previously pending claims 1, 2, 9, 22 and 26 have been amended and new claims 27-28 have been added. Claims 1-4, 9, 22, 26-28 are currently being examined.

2. The following rejections are maintained:

Claim Rejections - 35 USC § 112

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> "The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention."

4. Claims 1-4, 9, 22 26 remain rejected under 35 USC 112, first paragraph and newly added claims 27-28 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 9, Section 4, pages 3-5 and further for the reasons set forth below.

It is assumed for examination purposes that the limitation of "an amino acid sequence as depicted in SEQ ID NO:1" is meant to mean any sequence of two or more amino acids disclosed in SEQ ID NO:1. Thus claim 4 is drawn to chemokines that comprise two or more of the amino acid residues found in SEQ ID NO:1.

It is assumed for examination purposes that the limitation "vaccinating against a breast disease" recited in claims 9 and 26 is drawn to all breast diseases including cancer.

The claims are drawn to, claims 1-4, 9, 27, a method of treating breast disease, benign cystitis, benign hyperplasia, cancer and malignancies comprising administering to a patient an effective amount of a chemokine comprising SEQ ID NO:3, 4 or 5, **an** amino acid sequence as depicted in SEQ ID NO:1 (emphasis added), wherein the chemokine comprises a range of amino acid residues, a range of molecular weights, a range of isoionic points as well as, claims 22, 26, 28, a method for vaccinating against a breast disease , inflammation, infection, mastitis comprising administering to a patient an effective amount of a chemokine comprising SEQ ID NO:3, 4 or 5, wherein the chemokine comprises a range of amino acid residues, a range of molecular weights, a range of isoionic points.

The specification teaches that the present invention relates to a method of treating breast disease in a patient comprising administering to the patient an effective amount of a peptide (para bridging pages 4-5). The invention also relates to a method of vaccinating a patient against breast disease by administering an effective amount of an antigenic portion of a chemokine of the present invention. The present invention relates to an isolated chemokine that is preferentially expressed in breast tissue (p. 5, lines 30-31). The specification teaches a single putative chemokine, SEQ ID NO:1, of which the first 22 amino acids represents a leader sequence (p. 6, lines 19-30). The chemokines and peptides of the invention can be administered as a vaccine for preventing breast disease (p. 8, lines 1-3). Breast disease is meant to include (and thus is not limited to) various pathological states of the mammary gland such as inflammations, infections, mastitis, benign cystitis, benign hyperplasias, cancer and other malignancies (p. 8, lines 9-14). The specification exemplifies the isolation of a

novel human breast tissue specific nucleic acid sequence, its cloning and sequencing wherein the isolated molecule encodes SEQ ID NO:1 (pps. 34-35), the production of antibodies against the polypeptide encoded by the open reading frame of said novel nucleic acid sequence ((pps 37-38). BRST-24, an EST that is comprised within the polynucleotide encoding SEQ ID NO:1, is expressed in both normal breast and breast carcinoma tissue samples at identical concentrations (p. 46, see Table 1). It was found that the polypeptide encoded by the novel polynucleotide is found in sera of breast cancer patients but not in the sera of normal patients or in the sera of patients with prostate, ovarian or colon cancer (see Table 6, pg 51), clearly demonstrating that the expressed polypeptide is diagnostic for breast cancer.

One cannot extrapolate the teaching of the specification to the enablement of the claims because the method of treatment of breast disease is drawn to administration of a polypeptide, that is vaccination with said polypepide for the treatment of a variety of diseases. It appears that the method of treatment is drawn to active immunotherapy wherein the administration of the polypeptide would result in the activation of the immune system, that is antibodies and cytotoxic T cells that would presumably bind SEQ ID NO:1 (apparently less the 22 amino acid leader) and somehow treat the breast disease. However, the specification provides no exemplification of or guidance on how to use the claimed peptide/vaccine formulation for activity immunotherapy. Although drawn to the active immunotherapy of cancer, the teachings of Ezzell, Spitler and Boon are clearly relevant to all of the claimed and inferred breast diseases since the goal of tumor vaccination, and in fact the goal of all active immunotherapy vaccination, is the induction of disease/tumor immunity to prevent disease/tumor recurrence and to

eliminate residual disease. Ezzell (J. NIH Res, 1995, 7:46-49) reviews the current thinking in cancer vaccines and states that tumor immunologists are reluctant to place bets on which cancer vaccine approach will prove effective in the long run (see the entire document, particularly last paragraph) and further states that no one is very optimistic that a single peptide will trigger an immune response strong enough to eradicate tumors or even to prevent the later growth of micrometastases among patients whose tumors have been surgically removed or killed by radiation or chemotherapy (p 48, para 6). In addition, Spitler (Cancer Biotherapy, 1995, 10:1-3) recognizes the lack of predictability of the nature of the art when she states that "Ask practicing oncologists what they think about cancer vaccines and you're likely to get the following response: "cancer vaccines don't work". Ask a venture capitalist or the director of product development at a large pharmaceutical company and you're likely to get the same response." (p 1, para 1).

Furthermore, Boon (Adv Can Res, 1992, 58:177-210) teaches that for active immunization in human patients we have to stimulate immune defenses of organisms that have often carried a large tumor burden. Establishment of immune tolerance may therefore have occurred and it may prevent immunization and several lines of evidence suggest that large tumor burdens can tolerize or at least depress the capability to respond against the tumor (p. 206, para 2). Although the specification clearly demonstrates that breast cancer patients are found to have circulating SEQ ID NO:1 (presumably minus the 22 amino acid leader sequence), there is no suggestion in the specification that the presence of these antigens has resulted in autoantibodies against the antigen thus it would be highly unpredictable that administration of the antigen as a

cancer vaccine, into patients that already express a heavy load of the antigen in serum, would lead to an immune response against the tumor or any other breast disease whose etiology includes secretion of the claimed polypeptide into the bloodstream. Further, although it is well known that successful vaccines have been developed for a number of diseases other than cancer, in each of those cases, a nexus has been established between the antigen that is used for the active immunization and the disease itself. In the instant case, other than Applicant's listing of the diseases, no nexus has been established. Although Applicant has demonstrated a nexus between breast cancer and SEQ ID NO:1, no nexus has been established between SEQ ID NO:1 and any treatment of cancer. Clearly, given the teachings above drawn to treatment of cancer by active immunization, no one of ordinary skill in the art would believe it more likely than not that the claimed invention would function as claimed in the vaccine based treatment of any disease in the absence of objective evidence demonstrating that the invention will function as claimed. Further, one might ask why Applicant apparently feels that the claimed method would be useful for treating the diseases other than cancer wherein no nexus has been established between SEQ ID NO:1 and those diseases, given the complete lack of any information correlating the secreted polypeptide and the etiology of any of those diseases.

Further, as drawn to treatment of all of the diseases, the specification does not set forth sufficient teachings to allow one skilled in the art to use the claimed reagents and methods to effectively treat breast diseases. The specification does not provide teachings to establish effective dosages or methods of administration of the polypeptides so that they will function as claimed. The specification provides no

description of how to develop effective vaccines which elicit an immune response against the peptide and which effectively treat breast diseases. The specification provides no guidance on variables such as biological stability, half-life or clearance from the blood of the claimed polypeptide vaccine reagent, all of which are important parameters in achieving successful therapy. The peptide may be inactivated *in vivo* before producing a sufficient effect, for example, by proteolytic degradation, immunological activation or due to an inherently short half life of the protein. In addition, the products of any immune response to the peptide, that is antibodies and/or cytotoxic T cells may not reach the target because of the inability to penetrate tissues or cells where its activity is to be exerted, circulation into the target area may be insufficient to carry the immune response products, the products may be absorbed by cells and tissues where they have no effect and a large enough local concentration may not be established. This is of especial importance in the instant case because of the known secretion of the polypeptide product into the blood stream wherein it would be expected that the immune system products would be sequestered by the circulating antigens.

Further, as drawn specifically to the treatment of breast cancer/malignancies, the unpredictability of treatments for any type of cancer is well known in the art and one cannot extrapolate the teaching of the specification to the enablement of the claims because Gura (Science, 1997, 278:1041-1042) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile and teach that since formal screening began in 1955, many thousands of drugs have shown activity in either cell or animal models but

that only 39 have actually been shown to be useful for chemotherapy (p. 1041, see first and second para). Because of the known unpredictability of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the method comprising the administration of the claimed polypeptides would function as claimed based only upon the known secretion of SEQ ID NO:1 into the sera of breast cancer patients compared to normal controls. Further, the refractory nature of cancer to drugs is well known in the art. Jain (Sci. Am., 1994, 271:58-65) teaches that tumors resist penetration by drugs (p.58, col 1) and that scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors (p. 65, col 3). Curti (Crit. Rev. in Oncology/Hematology, 1993, 14:29-39) teaches that solid tumors resist destruction by chemotherapy agents (which clearly include immune response products generated against polypeptides) and that although strategies to overcome defense mechanisms of neoplastic cells have been developed and tested in a number of patients, success has been limited and further teaches that it is certainly possible that cancer cells possess many as yet undefined additional molecular mechanisms to defeat chemotherapy treatment strategies and if this is true, designing effective chemotherapeutic regimens for solid tumors may prove a daunting task (para bridging pages 29-30) and concludes that knowledge about the physical barriers to drug delivery in tumors is a work in progress (p. 36, col 2). It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the method comprising the administration of the claimed polypeptides would function as claimed based only upon the known secretion of the

SEQ ID NO:1 polypeptide into the serum of breast cancer patients compared to normal controls. It is clear, as disclosed above that the specification does not teach how to use the claimed polypeptides for the treatment of any breast disease. Further, as drawn specifically to peptides for cancer immunotherapy, Bellone et al (Immunology Today, 1999, 20:457-462) specifically teach the difficulties of using peptides for cancer immunotherapy, that is that there is usually a poor correlation between induction of specific T cells and clinical responses (para bridging. 457-459) and specifically lists the disadvantages of using peptides which include no direct evidence for a role in tumor rejection, applicability to few patients, risk of generating tumor escape mutants, risk of autoimmune reactions (p. 461, Box 1).

Finally, claims 22, 26, 28 are all drawn to a method for vaccinating against a breast disease in a patient in need thereof. The claims as broadly written read on both treatment of breast disease and on the prevention of breast disease. The limitations drawn to treatment of breast disease have been discussed above. As drawn to disease prevention, the specification provides no guidance on which breast diseases could be prevented by administration of the claimed polypeptides. The specification provides no guidance on how to identify the patients which are in need of vaccination for the prevention of disease. The specification provides no guidance on any protocols for prevention, that is, when the method should be started or what dosages of the vaccine are required in order for the invention to function as claimed. In the absence of objective evidence, no one of ordinary skill in the art would believe that it is more likely than not that the claimed invention would function as claimed based only on the know presence of the mature SEQ ID NO:1 in the sera of cancer patients as compared

with normal controls. The specification provides insufficient guidance with regard to these issues and provides no working examples which would provide guidance to one skilled in the art and no evidence has been provided which would allow one of skill in the art to predict that the invention would function as claimed with a reasonable expectation of success. In view of the above, one of skill in the art would be forced into undue experimentation to practice the claimed invention.

Applicant's arguments drawn to the rejection of claims 1-9, 9, 22 and 26 are relevant. Applicant argues that in view of the absence of any evidence provided by the Examiner that the claimed method of treating will not work for any breast disease, the rejection is improper and there is no requirement that the claims be restricted to working examples. Applicant quotes the MPEP and case law which discloses that Applicants are not required to disclose every species encompassed by their claims, even in an unpredictable art. The argument has been considered but has not been found persuasive, Examiner has provided sound scientific reasoning as to why the invention would not work for any breast disease. Further, Examiner has provided evidence supporting the sound scientific reasoning previously set forth. Although Applicant quotes the MPEP and case law to demonstrate that working examples are not required it is absolutely clear, given the above, that this is an undeveloped art. MPEP 2164.02 clearly states that in the case of an undeveloped art, lack of a working example, that is lack of sufficient guidance, is a factor that must be considered in determining enablement of the claims. In this particular case, no nexus between any breast disease, other than breast cancer, and the mature SEQ ID NO:1 has been established. None of scientific reasoning, prior art information, *in vitro* or *in vivo*

evidence has been provided that would even suggest that it would be possible to treat breast cancer with the instant method as claimed. Finally, MPEP 2164.03 specifically states that the amount of guidance or direction needed to enable the invention is inversely related to the amount of knowledge in the state of the art as well as the predictability in the art. If little is known in the prior art about the nature of the invention and the art is unpredictable, the specification would need more detail as to how to make and use the invention in order to be enabling. In view of the lack of guidance, the undeveloped nature, the clearly established unpredictability of the art, undue experimentation would be required to practice the claimed invention.

Applicant further argues that this application actually describes and enables methods for treating a large number of different breast diseases and points to page 5, lines 6-9 and page 8, lines 9-12. The argument has been considered but has not been found persuasive because a review of page 5, lines 6-9 reveals support for "peptides.....of the present invention are useful in the early detection of various pathological states". A review of page 8, lines 9-12 reveals support for "The antibodies and binding portions thereof can be used to detect breast disease in a patient." The specification does on to list breast diseases included for the method of detection. Examiner fails to understand how the teaching drawn to the detection either enables or describes methods for treating a large number of different breast diseases. Clarification is required.

Applicant further argues that Examiner has not made a *prima facie* case for lack of enablement and again cites the MPEP. Applicant further states that Examiner has failed to provide any references to support the enablement rejection and has provided

only faulty technical reasoning and Examiner's conclusions are incorrectly based because of the demonstration of preferential expression in breast and the finding of mature SEQ ID NO:1 in the sera of individuals with breast cancer. The argument has been considered but has not been found persuasive. Examiner's scientific reasoning is sound and fully supported by what is known in the art as set forth above. No one of ordinary skill in the art would believe it more likely than not that the claimed invention will function as claimed based only on the preferential expression of SEQ ID NO:1 in breast and the secretion of the mature polypeptide into the sera of breast cancer patients. The arguments have not been found persuasive and the rejection is maintained.

5. Claims 1, 2, 4, 9, 22 26 remain rejected under 35 USC 112, first paragraph and claims 3, 27-28 are rejected under 35 USC 112, first paragraph for the reasons previously set forth in Paper No. 9, Section 5, pages 5-7 and further for the reasons set forth below.

It is assumed for examination purposes that the limitation of "an amino acid sequence as depicted in SEQ ID NO:1" is meant to mean any sequence of two or more amino acids disclosed in SEQ ID NO:1. Thus claim 4 is drawn to chemokines that comprise two or more of the amino acid residues found in SEQ ID NO:1.

Claims 1-4, 9, 22 26-28 are drawn to a method of treating breast disease in a patient in need thereof comprising administering an effective amount of a chemokine which comprises SEQ ID NO:3, 4, 5 or an amino acid sequence found in SEQ ID NO:1, a method of vaccinating against a breast disease. Although drawn to DNA arts, the findings in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43

USPQ2d 1398 (Fed. Cir. 1997) and Enzo Biochem, Inc. V. Gen-Probe Inc. are relevant to the instant claims. The Federal Circuit addressed the application of the written description requirement to DNA-related inventions in University of California v. Eli Lilly and Co., 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). The court stated that "[a] written description of an invention involving a chemical genus, like a description of a chemical species, 'requires a precise definition, such as by structure, formula, [or] chemical name,' of the claimed subject matter sufficient to distinguish it from other materials." Id. At 1567, 43 USPQ2d at 1405. The court also stated that

> a generic statement such as "vertebrate insulin cDNA" or "mammalian insulin cDNA" without more, is not an adequate written description of the genus because it does not distinguish the genus from others, except by function. It does not specifically define any of the genes that fall within its definition. It does not define any structural features commonly possessed by members of the genus that distinguish them from others. One skilled in the art therefore cannot, as one can do with a fully described genus, visualize or recognize the identity of the members of the genus. A definition by function, as we have previously indicated, does not suffice to define the genus because it is only an indication of what the gene does, rather than what it is.

Id. At 1568, 43 USPQ2d at 1406. The court concluded that "naming a type of material generally known to exist, in the absence of knowledge as to what that material consists of, is not a description of that material." Id.

Finally, the court addressed the manner by which a genus of cDNAs might be described. "A description of a genus of cDNAs may be achieved by means of a recitation of a representative number of cDNAs, defined by nucleotide sequence, falling within the scope of the genus or of a recitation of structural features common to

the members of the genus, which features constitute a substantial portion of the genus." Id.

The Federal Circuit has recently clarified that a DNA molecule can be adequately described without disclosing its complete structure. See Enzo Biochem, Inc. V. Gen-Probe Inc., 296 F.3d 1316, 63 USPQ2d 1609 (Fed. Cir. 2002). The Enzo court adopted the standard that "the written description requirement can be met by 'show[ing] that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics ....i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. " Id. At 1324, 63 USPQ2d at 1613 (emphasis omitted, bracketed material in original).

Although the inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a product itself logically cannot adequately describe a method of using that product.

Thus, the instant specification may provide an adequate written description of the "chemokine" useful for treating breast disease, per Lilly by structurally describing a representative number of chemokines which are useful for treating breast disease or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics, functional characteristics when coupled with a

known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the chemokines required to practice the method of the claims in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide the complete structure of any chemokine other than SEQ ID NO:1, nor any functional characteristics drawn to a breast disease coupled with a known or disclosed correlation between structure and function. The disclosure of SEQ ID NO:1 does not provide a description of chemokines which are useful for treating a breast disease that would satisfy the standard set out in Enzo.

The specification also fails to describe the chemokines which are capable of treating breast cancer by the test set out in Lilly. The specification describes only a single chemokine. Therefore, it necessarily fails to describe a "representative number" of such species. In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the chemokines that are useful to treat breast disease that is required to practice the claimed invention. Since the specification fails to adequately describe the product used in the method, it also fails to adequately describe the claimed method.

Further, although the inventions at issue in Lilly and Enzo were DNA constructs per se, the holdings of those cases are also applicable to claims such as those at issue here. A disclosure that does not adequately describe a method of treating/vaccinating

against a disease cannot adequately describe a method of treating/vaccinating against that disease.

Thus, the instant specification may provide an adequate written description of the methods of treating/vaccinating against breast disease, per Lilly by structurally describing a representative number of protocols and diseases to be treated or by describing "structural features common to the members of the genus, which features constitute a substantial portion of the genus." Alternatively, per Enzo, the specification can show that the claimed invention is complete "by disclosure of sufficiently detailed, relevant identifying characteristics of the method, functional characteristics of the method ,when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics."

In this case, the specification does not describe the methods of treatment or provide any nexus between methods of treatment and the diseases disclosed and claimed required to practice the method of the claims in a manner that satisfies either the Lilly or Enzo standards. The specification does not provide any protocols for treatment, does not even provide any nexus between SEQ ID NO:1 and any disease other than breast cancer. There are not any functional characteristics of the method disclosed coupled with a known or disclosed correlation between structure and function. The disclosure of SEQ ID NO:1 does not provide a description of the claimed methods would satisfy the standard set out in Enzo.

The specification also fails to describe the claimed methods by the test set out in Lilly. The specification describes does not describe any method of treatment. Therefore, it necessarily fails to describe a "representative number" of such species.

In addition, the specification also does not describe "structural features common to the members of the genus, which features constitute a substantial portion of the genus."

Thus, the specification does not provide an adequate written description of the methods of treating/vaccinating against breast disease that is required to practice the claimed invention.

As drawn to the rejection of claims 1, 2, 4, 9, 22 and 26, Applicant argues as follows.

Applicant argues that the amended claims specify methods that involve detecting the expression of a chemokine having at least a partial amino acid sequence of SEQ ID Nos 3, 4, 5 and chemokines are well known in the art. The argument has been considered but has not been found persuasive because Applicant is arguing limitations not recited in the claims as currently constituted. It is suggested that Applicant review the claims submitted with the response.

The arguments have been considered but have not been found persuasive and the rejeciton is maintained.

New Grounds of Objection

Specification

6. The specification on page 1 should be amended to reflect the status of the parent applications.

7. All other objections and rejections recited in Paper No. 9 are hereby withdrawn.

8. No claims allowed.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Ungar, PhD whose telephone number is (703)

305-2181. The examiner can normally be reached on Monday through Friday from 7:30am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached at (703) 308-3995. The fax phone number for this Art Unit is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Effective, February 7, 1998, the Group and/or Art Unit location of your application in the PTO has changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1642.

Susan Ungar
Primary Patent Examiner
November 14, 2003